



**STATE PROCUREMENT OFFICE
NOTICE OF AND REQUEST FOR EXEMPTION
FROM CHAPTER 103D, HRS**

1. TO: Chief Procurement Officer

2. FROM: HEALTH/STATE LABORATORIES/MEDICAL MICROBIOLOGY

Department/Division/Agency

Pursuant to §103D-102(b)(4), HRS, and Chapter 3-120, HAR, the Department requests a procurement exemption to purchase the following:

<p>11 MAY 12 08 40 STATE PROCUREMENT OFFICE STATE OF HAWAII</p>	<p>3. Description of goods, services or construction: HIV EIA TEST KITS & WESTERN BLOT TEST KITS</p>
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<p>4. Name of Vendor: Bio-Rad Laboratories, Inc. Address: 1000 Alfred Nobel Drive Hercules, CA 94547</p>	<p>5. Price: \$175,000</p>
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<p>6. Term of Contract: From: CPO APPROVAL To: 12 MONTHS</p>	<p>7. Prior Exemption Ref. No. 11-030-K</p>
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8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State: State Laboratories' equipment and instrumentation is proprietary to Bio-Rad Laboratories. No other products are USFDA approved to be used with this equipment.

The tests to be purchased are USFDA approved for screening of human serum, plasma, and cadaveric serum for antibodies to the Human Immunodeficiency Virus (HIV) Types 1 (Groups M and O) and/or 2 (HIV-1/HIV-2). These agents have been identified as causative agents of Acquired Immunodeficiency Virus Syndrome (AIDS). This product, from Bio-Rad Laboratories, who acquired Sanofi Diagnostics Pasteur, is marketed by their Genetic Systems division, (See Attached Sheet)

9. Details of the process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:

There is now currently only one USFDA approved manufacturer of an HIV-1/HIV-2 by Enzyme Immunoassay (EIA), the Genetic Systems HIV-1/HIV-2 + O EIA test manufactured/distributed by Bio-Rad Laboratories, when the only other manufacturer, Abbott Laboratories, discontinued their product in March 2011, to offer a new 4th generation assay, Abbott HIV-1/2 Ag/Ab (Antigen/Antibody) Combo test.

There are currently 2 USFDA approved supplementary/confirmatory tests by western blot for use on HIV-1 serum screen test reactive specimens. We are requesting to have the Bio-Rad HIV-1 Western Blot Test available for contingency use (See Attached Sheet)

10. A description of the agency's internal controls and approval requirements for the exempted procurement:

The approval process within the Communicable Disease Division (CDD) for purchases >\$5,000 requires CDD Chief or designee approval. The CDD PHAO, Mr. Kevin Nomura, will be responsible for administering/monitoring this procurement for the STD/AIDS Branch with assistance from the SLD's Medical Microbiology Branch Chief, Ms. Gail Kunimoto.

5158

8. Explanation describing how procurement by competitive means is either not practicable or advantageous to the State:

uses recombinant and synthetic peptide antigens. The use of this type of antigen is believed to yield sensitive results, without a large number of false positives.

This product is intended to be used to screen oral fluid specimens by enzyme immunoassay in our laboratory. Our laboratory validated the use of a serum-based EIA in order to maintain testing of oral fluid specimens ("off-label use"), which has shown to yield better sensitivity and specificity for HIV antibodies than that of other alternative body fluids to serum. In addition, we will be using this product to differentiate the presence of HIV-1 and HIV-2 antibodies from specimens being screened by the new 4th Generation HIV-1/2 Ag/Ab Combo Test manufactured by Abbott Laboratories which will allow for early detection of HIV infection.

Avioq, Inc. announced FDA approval of their HIV-1 EIA with serum and oral fluids specimens in October 2009, however, it is only approved to detect HIV-1 antibody and not HIV-2 antibody and their product cannot be used to screen blood donors. Procurement by competitive means is not practicable or advantageous to the State since our current algorithm for testing allows detection for both HIV-1 and HIV-2 antibodies.

There are currently only two (2) USFDA approved supplementary or confirmatory tests by western blot for use on HIV-1 serum screen test reactive specimens. The USFDA approved western blot test kits are the Cambridge Biotech HIV-1 Western blot Test Kit manufactured and distributed by Maxim Biomedical, Inc. and the Bio-Rad HIV-1 Western Blot Test Kit. Procurement by competitive means for the Bio-Rad HIV-1 Western Blot Test Kit is not advantageous to the State because our laboratory already performs the Cambridge Biotech Western Blot Test as the primary supplementary/confirmatory test for HIV antibody screen reactive specimens.

We are requesting to have the Bio-Rad HIV-1 Western Blot Test available for contingency use, as may be needed, if the test of the only competitor, Cambridge Biotech HIV-1 Western Blot, becomes unavailable or has quality assurance issues.

9. Details of process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:

so we will have both manufacturer's products available in our laboratory thereby ensuring fair and open competition as practicable.

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS
Human Immunodeficiency Virus EIA Test Kits and Western Blot Test Kits
April 26, 2011
Page 3

Full validation of the serum EIA test kit to be used with oral fluid specimens was a huge undertaking for this laboratory in order to meet very stringent criteria requirements by federal law for validation of an off-label product. Our laboratory completed the full validation/comparison study using the Bio-Rad HIV-1/2 + O EIA Test Kit with oral fluid specimens and not the short-term interim proposal by the Association of Public Health Laboratories approved by the Centers for Medicare and Medicaid Services (CMS).

Bio-Rad Laboratories manufactures and is the sole distributor of the Genetic Systems HIV-1/2 + O EIA Test Kit. Our laboratory selected to validate this product for use with oral fluid specimens for detection of HIV-1/2 antibodies based on current available information.

D.F. 11-089-D

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

12. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:		
Name	Position	Involvement in Process
Venie Lee	Acting STD Program Coordinator	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Kevin Nomura	CDD PHAO	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Peter Whitarcar	STD/AIDS Branch Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Dr. Glenn Wasserman	Communicable Disease Div. Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration

13. Direct inquiries to:	Department: Health Contact Name: Gail Y. Kunimoto Phone Number: 453-6700 Fax Number: 453-6716
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Agency shall ensure adherence to applicable administrative and statutory requirements

14. I certify that the information provided above is, to the best of my knowledge, true and correct.


 Department Head

5/11/11
 Date

Reserved for SPO Use Only

15. Date Notice Posted 5/13/11

The Chief Procurement Officer is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, within seven calendar days or as otherwise allowed from the above posted date to:

Chief Procurement Officer
 State Procurement Office
 P.O. Box 119
 Honolulu, Hawaii 96810-0119

Chief Procurement Officer's comments:

Request has been withdrawn by the department.

16. APPROVED DISAPPROVED **NO ACTION REQUIRED**


 Chief Procurement Officer 5/18/2011
 Date